



Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	CAPIO SLIM Suture Capturing Device
Device Model	M0068318250
Lot No.	30367934
	30362314
Manufacturer	Boston scientific
Country of Origin	USA
Reference	<u>Link</u>
Reason of Recall	NHRA initiates this FSN due to reports of Capio™ SLIM Suture Capturing Devices not catching the suture needle/dart as expected. Certain tooling used in manufacturing may have affected component dimensions, impacting device functionality. The most serious risk is hemorrhage, which may require additional medical intervention.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Gulf corporation for Technology W.L.L at quality@gctbahrain.com to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Recall 2024 0020 09/Jul/2024